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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,017	04/12/2007	Hongping Ye	09548.1031USWO	6903
52835 7590 11/23/2007 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902			EXAMINER DENTZ, BERNARD I	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 11/23/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/581,017

Applicant(s)

YE ET AL.

Examiner

Bernard Dentz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

The restriction requirement is made final because applicants' claims include old compounds as explained below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kogen et al, US Patent 5,451,688. See compounds I-53, I-63, I-65 and I-66 in Table 1. The compounds are made from pravastatin the same starting materials as in this application. See p. 6 of the specification. See col. 22 under REACTION SCHEME A. There it states that the "starting material, the compound of formula (VI), may be the known compound pravastatin, in which the hydroxyl group at the 6-position is in the beta-configuration. The stereochemistry of the corresponding groups at the 6-position is retained as the beta-configuration throughout the whole of the reaction scheme. Alternatively, an epimeric isomer at the 6-position of pravastatin may be used as the starting material in Step A1, in which case it is possible to prepare the desired compounds of formulae (X), (X1) and (XII) in which the substituents at the 6-position are in the alpha-configuration. Although the stereochemistry at the 6- and other positions is not shown in the following formulae, the present invention envisages the use either of individual isolated isomers, e.g. pravastatin or its epimer, or mixtures of these isomers."

Kogen's method of synthesis although different than applicants' synthesis occurs without change of configuration at other asymmetric positions . See EX. A, step A- 1 e. g.

See Ex. 24, 45,51,68 and 81 for the synthesis and properties of compounds which meet the instant compounds of Formulae I and II.

Note the recitation starting at the bottom of col. 39 that the compounds of formula II containing 2 hydroxy groups can be protected simultaneously by a diol protecting group such as isopropylidene. This anticipates the compounds of (a) where W is the third value. The compounds where W is the second value (the metal salts) are anticipated at the top of col. 44.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sankyo, Jpn. 59175450. It prepares the instant compound by incubating ML-236A with microorganisms capable of 3- or 6-hydroxylation of ML-236A. See p. 1 for the structure of the anticipating compound and p. 3 and 4 of the attached print-out from an online Chem. Abstracts search. The original patent is supplied as well. An English translation will be available in the near future. Note that the stereochemistry is the same.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 571-272-0683. The examiner can normally be reached on Mon-Fri from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dentz

BERNARD DENTZ  
PRIMARY EXAMINER

11-19-2007